Re-evaluation Note REV2016-09

Special Review of Simazine: Proposed Decision for Consultation

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1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) has initiated a special review of pest control products containing simazine based on the decisions taken by Norway in 1998 and by the European Commission in 2004. The initiation of the special review under the *Pest Control Products Act* was announced in December 2013 (Canada, 2013).

Pursuant to subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspects of concern that prompted the special review of pest control products containing simazine. The aspects of concern are relevant to the environment and were 1) related to persistence, mobility and the exceedance of simazine and its chlorinated transformation products above the European Union (EU) regulated threshold of 0.1 µg/L in groundwater (related to the potential leaching of simazine and its chlorinated transformation products into groundwater) and 2) toxicity to algae.

2.0 Uses of Simazine in Canada

Simazine is a broad-spectrum triazine herbicide. It is currently registered for a wide variety of uses (for example, fruits, corn, shelter belts, woody ornamentals and nursery stock, woodlots). It is applied by ground equipment. In Canada, simazine underwent re-evaluation in 2010 (Canada, 2009; Canada, 2010). Appendix I lists all simazine products that are currently registered under the authority of the *Pest Control Products Act*. The technical grade active ingredients and all end-use products containing simazine are considered in this review. The proposed special review decision is applicable for all registered pest control products containing simazine.

3.0 Aspects of the Pest Control Product that Prompted the Special Review

The use of simazine in Norway was banned in 1998 due to environmental concerns, namely *"High mobility, persistence in soil and water, extremely toxic to algae."* (Rotterdam Convention, 2001). The use of simazine in European Union Member States was banned in 2004 due to environmental concerns (European Commission, 2003; European Commission, 2004). The European Commission concluded that "*the available monitoring data were insufficient to demonstrate that in large areas concentrations of the active substance and its breakdown products will not exceed 0.1 µg/l in groundwater. Moreover it cannot be assured that continued use in other areas will permit a satisfactory recovery of groundwater quality where concentrations already exceed 0.1 µg/l in groundwater*". The Rotterdam Convention Prior Informed Consent (PIC) Circular XXI (Rotterdam Convention, 2005) also provided similar information and indicated that the reasons for the European Union regulatory action were relevant to the environment.

Based on the review of the Norwegian and European Commission decisions, the aspects of concern that prompted the special review of simazine are 1) related to the persistence, mobility and the potential leaching of simazine and its chlorinated transformation products (desisopropylatrazine (DIA), also referred to as deethylsimazine, and diaminochlorotriazine (DACT), also referred to as desethyl-desiopyropyl atrazine or DDA) into groundwater and 2) toxicity to algae.

4.0 PMRA Evaluation of the Aspects of the Pest Control Product that Prompted the Special Review

Following the initiation of the special review of simazine, the PMRA requested information related to the aspects of concern from provinces and other relevant federal departments and agencies, in accordance with subsection 18(2) of the *Pest Control Products Act*. Information related to water monitoring of simazine and its chlorinated transformation products (DIA and DACT) was received and was considered in the special review.

In order to evaluate simazine's persistence, mobility, potential for leaching into groundwater and toxicity to algae, the PMRA has considered currently available relevant information (for example, environmental fate and toxicity information, available Canadian and American groundwater monitoring data and water modelling). No concerns related to the aspects of concern were identified in the information received through the Canadian incident report database.

4.1 Persistence, Mobility and Potential for Leaching into Groundwater

The PMRA has considered the transformation and mobility of simazine and its chlorinated transformation products (Canada, 2009). Simazine has been reported to have a low solubility in water of 6.2 mg/L (pH 7, 20°C). Based on its vapour pressure (2.21×10^{-8} mmHg at 25°C) and Henry's law constant (5.6×10^{-5} Pa.m^3.mol^{-1}), simazine is not expected to volatilize significantly from moist soils or water surfaces. Simazine has a low potential for bioaccumulation based on its log K_{ow} of 2.1 and based on a bioconcentration factor of 0.9× in rainbow trout viscera and of 2.3× in rainbow trout muscle.

Simazine is expected to be persistent in the environment. Hydrolysis is not a primary route of transformation of simazine (stable in aqueous solution at pH 4, pH 7 and pH 9 at 20°C). Photo-transformation in water is also not a primary route of transformation of simazine (half-life of 97 days at 25°C). Based on laboratory aerobic biotransformation studies in soil, simazine will metabolize in aerobic soil with a half-life of 91 days. Based on laboratory aerobic biotransformation studies in water-sediment (aquatic) systems, simazine will slowly metabolize with a half-life of 71.2 days. Under anaerobic aquatic conditions simazine is persistent (half-life of 664 days). The USEPA has reported similar conclusions with respect to the fate of simazine in the environment (United States, 2013a). Furthermore, the transformation products DIA and DACT have been detected in some environmental fate laboratory studies (in aerobic soil, 10-18% of applied simazine was transformed into DIA and 1-9% of applied simazine was transformed into DACT). DIA was also detected in field studies (United States, 2013a).

Simazine is mobile in soil. The adsorption/desorption characteristics of ^{14}C-labelled simazine were reported in eight soils, varying in organic matter and texture in batch equilibrium studies. The adsorption coefficients were between 0.48 and 4.31, and the desorption coefficients were between 0.78 and 15.5, indicating that simazine was not strongly adsorbed onto soil and that it was easily desorbed from soil. The chlorinated transformation products of simazine (DIA and DACT) are highly mobile to very highly mobile in soil. Therefore, the PMRA has concluded that simazine and its chlorinated transformation products have the potential to leach into groundwater. Simazine meets the Toxic Substances Management Policy (TSMP) Track 1 criteria for persistence in water (half-life of 664 days in anaerobic water systems exceeds the TSMP Track 1 cut-off criteria of >182 days for water); however, simazine is not a TSMP Track 1 substance as it does not meet all Track 1 criteria (Canada, 2009).

Residues of simazine and its chlorinated transformation products (DIA and DACT) in potential groundwater drinking water sources were estimated using modelling (Pesticide Root Zone Model Groundwater (PRZM-GW)) and monitoring data. The modelled estimated environmental concentrations (EECs) were based on the maximum yearly application rate. The acute EEC in ground water was 930 µg/L of the combined residues of simazine, DIA and DACT (90th percentile of daily average concentrations) and the chronic EEC was 903 µg/L (90th percentile of yearly average concentrations).

Modelled levels in groundwater are conservative and expected to exceed actual levels. Groundwater monitoring data from both Canada and the United States were used to assess the potential leaching of simazine and its chlorinated transformation products into groundwater. The PMRA considered the available monitoring data for simazine and its chlorinated transformation products DIA and DACT (referred to as total simazine) in potential drinking water sources in Canada and the United States. These monitoring data show that these compounds were detected in 2,900 out of a total of approximately 22,300 groundwater samples (13%) from Canada and the United States. The highest concentrations detected were 18 µg/L and 8.9 µg/L of DIA in two groundwater samples from the United States. The next highest concentration detected was 7.83 µg/L (total simazine), also from a groundwater sample from the United States. When considering only Canadian data, the maximum concentration of total simazine detected in groundwater was 1.74 µg/L. The higher monitoring levels detected in the United States may reflect a higher use of simazine in that country. Based on the available monitoring data, groundwater samples in Canada and the United States contain total simazine levels considerably lower than the modelled estimates presented above.

4.1.1 Drinking Water Risk Assessment

In addition to assessing the potential leaching of simazine and its chlorinated transformation products into groundwater, the PMRA conducted acute and chronic drinking water risk assessments to determine whether exposure to simazine and its chlorinated transformation products through Canadian groundwater presents a potential risk of concern. Acute drinking water exposure was addressed by incorporating modelled EEC values of simazine, DIA and DACT in the acute aggregate exposure assessment (food plus drinking water), while monitoring data were used for the chronic assessment. Using the acute reference dose (ARfD) for simazine of 0.1 mg/kg bw/day for females (ages 13-49), based on a no-observed-adverse effect level

(NOAEL) of 30 mg/kg bw/day and a composite assessment factor (CAF) of 300, the acute aggregate exposure from food and water (EEC value = 930 µg a.i./L, Level I) was calculated as 52.3% of the ARfD, which is not of concern. Similarly, using the acceptable daily intake (ADI) for simazine of 0.006 mg/kg bw/day, based on a NOAEL of 1.8 mg/kg bw/day and a CAF of 300, the chronic aggregate exposure from food and water (based on groundwater monitoring data) ranged from 15.9% to 84.6% of the ADI for all population subgroups and is not of concern.

Simazine, atrazine, and their common transformation products (DEA, DIA, DACT) share a common toxicity endpoint (neuroendocrine and neuroendocrine-related developmental and reproductive effects) and a known mechanism of toxicity for this endpoint, namely that they can cause a disruption of the hypothalamic-pituitary-gonadal axis in rats by alteration of levels of luteinizing hormone (United States, 2006c; United States, 2013b). The PMRA has previously considered triazine cumulative exposure via drinking water during the re-evaluation of simazine (Canada, 2009), which was based on a 2006 USEPA assessment (United States, 2006c). Using monitoring data or modelling, exposure was estimated based on data from three U.S. regions where exposure to triazine residues were likely to co-occur and which were representative of high-end exposure scenarios. Intermediate-term drinking water risk was estimated using the Cumulative and Aggregate Risk Evaluation System (CARES). Acceptable margins of exposure (MOEs), ranging from 760 to 84 399 (target MOEs of 300 and 1000) were reported for infants (younger than 1 year old), children (1-2 years old), females (13-49 years old) and males (20-49 years old), which represented the most vulnerable and sensitive groups relative to the endpoint of concern (NOAEL of 1.8 mg/kg/day) (United States, 2006c). Therefore, cumulative exposure to triazine residues through drinking water exposure is not of concern to human health. The USEPA's assessment is considered to be relevant to the Canadian situation, because Canadian maximum application rates are encompassed by those assumed in the USEPA's assessment. Currently, an updated cumulative assessment is ongoing as part of the USEPA Registration Reviews for simazine, atrazine and propazine and the PMRA will monitor the outcome of the revised assessment when it becomes available for public comment (United States, 2013b).

In 1998, the European Union adopted a level of 0.1 µg/L as the maximum acceptable concentration in groundwater for individual pesticides in 1998 (Annex I of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1998). The 0.1 µg/L threshold is a legislated, rather than risk-based, value that applies to all pesticides regardless of their toxicity to humans. Conversely, the PMRA follows a risk-based scientific approach in determining the risk to human health from pesticides in drinking water. This approach takes into consideration both the estimated level in drinking water sources (exposure) and the toxicity of the pesticide. Based on the drinking water risk assessment of simazine and its chlorinated transformation products, the PMRA concludes that there are no acute or chronic risks of concern from groundwater under the current conditions of use.

However, to minimize the potential leaching of simazine and its chlorinated transformation products, the labels of all registered end-use products containing simazine currently include an environmental hazard statement to reduce the potential for leaching of simazine into groundwater.

4.2 Toxicity to Algae

The most sensitive non-vascular aquatic plant is the freshwater blue-green algae (*Anabaena flos-aquae*) with an EC_{50} of 36 µg/L based on reduction in growth rates observed by day 5 (Canada 2009, United States 2006a, United States 2013a).

In order to characterize potential risk to algae, EECs were calculated using modeling (Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS)) based on application rates ranging from 3.36 kg a.i./ha to 10.76 kg a.i./ha (Canada, 2009; United States, 2006). Risk quotients (RQs) were calculated by dividing these modelled EECs with the EC_{50} of 36 µg/L (from the most sensitive algae, *Anabaena flos-aquae*). Based on this, the level of concern (LOC) was exceeded for algae (RQs ranged from <LOC to 9.33; LOC of 1.0). Based on the highest concentration of simazine detected by monitoring of surface water in Canada (23 µ/L), the RQ does not exceed the LOC of 1.0. Although the assessment based on modelled EECs was conservative, the PMRA implemented risk reduction measures to minimize the potential exposure of algae to simazine from spray drift and runoff (buffer zones for field sprayer application for the protection of aquatic habitats and advisory statements to minimize runoff and aquatic exposure). Based on the results of the risk assessment and taking into consideration the current conditions of use, the potential risk to algae is not expected to be of concern.

5.0 Proposed Special Review Decision for Simazine

Evaluation of available relevant scientific information related to the aspects of concern indicates that simazine and its chlorinated transformation products do not pose unacceptable risks to human health and the environment, with respect to drinking water and risk to algae, taking into account current conditions of use. On this basis, the PMRA, under the authority of the *Pest Control Products Act*, is proposing to confirm the current registration of pest control products containing simazine for sale and use in Canada. This proposal affects all registered products containing simazine in Canada.

This proposed special review decision is a consultation document.[1] The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

6.0 Next Steps

Before making a special review decision on simazine, the PMRA will consider any comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on simazine. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and the PMRA's response to these comments.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Appendix I Registered Products Containing Simazine as of 18 May 2016

Registration Number	Marketing Class	Registrant	Product Name
21968	Technical	Adama Agricultural Solutions Canada Ltd.	Simanex (Simazine) Technical
23052	Technical	Syngenta Canada Inc.	Simazine Technical
15902	Commercial	Bayer Cropscience Inc.	Simadex Simazine Flowable
16370	Commercial	Syngenta Canada Inc.	Princep Nine-T Herbicide
23181	Commercial	Loveland Products Canada Inc.	Simazine 480 Herbicide

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1873824	Canada, 2010. Pest Management Regulatory Agency Re-evaluation Decision, RVD2010-01, *Simazine*.
2405939	Canada, 2013. Pest Management Regulatory Agency Re-evaluation Note REV2013-06, *Special Review Initiation of 23 Active Ingredients*.
	European Commission, 2003. Review report for the active substance simazine finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 October 2003 in support of a decision concerning the non-inclusion of simazine in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance, SANCO/10495/2003-rev. Final, 10 September 2003.
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